

BEFORE USING PRODUCT, READ THE FOLLOWING IMPORTANT INFORMATION.

This booklet is designed to assist in using the HammerTube™ System. It is not a reference for surgical techniques.

CAUTION

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

GENERAL DESCRIPTION

The HammerTube™ System is comprised of a sterile, PEEK (Polyetheretherketone) fixation device and stainless steel K-wires. The PEEK implants are offered in diameters of Ø2.75mm and Ø3.50mm, with 0° and 10° angled options. The K-wires range in diameters from Ø1.2mm to Ø1.8mm. The system instruments include inserters, drills, planers, trephine removal tool, and a threaded extractor.

IMPLANT MATERIALS

The dowels are manufactured from PEEK per ASTM F2026 with a titanium plasma spray that conforms to ASTM F1580. The K-wires are manufactured from Stainless Steel per ASTM F138. The instrumentation is manufactured from medical grade stainless steels and plastics.

INDICATIONS FOR USE

The HammerTube™ System is indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the device.

The implantable K-wires are indicated for use in the stabilization and fixation of small bones for use in bone reconstruction, osteotomy, arthrodesis, fracture repair and fixation, appropriate for the size of the device. Additionally, the implantable K-wires are indicated as guide pins for insertion of instruments and implants in the HammerTube™ System.

CONTRAINDICATIONS

The HammerTube™ System is contraindicated for use in patients with an active or suspected infection; in patients who are physiologically or psychologically inadequate; in patients previously sensitized to titanium; in patients with insufficient quantity or quality of bone to permit stabilization of the bony segments; in patients with high level of activity; or where there is a possibility for conservative treatment.

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

In any surgical procedure, the potential for complications and adverse reactions exist. The risks and complications with these implants include:

- Loosening, deformation or fracture of the implant
- Acute post-operative infections and late infections with possible sepsis
- Migration, subluxation of the implant with resulting reduction in range of movement
- Fractures resulting from unilateral joint loading
- Thrombosis and embolism
- Wound hematoma and delayed wound healing
- Temporary and protracted functional neurological perturbation
- Tissue reactions as a result of allergy or foreign body reaction to dislodged particles
- Corrosion with localized reaction and pain
- Pain, a feeling of malaise or abnormal sensations due to the implant used
- Bone loss due to stress shielding

All possible complications listed here are not typical of Paragon 28, Inc. products but are in principle observed with any implant. Promptly inform Paragon 28, Inc. as soon as complications occur in connection with the implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality or mechanical stability is suspected, please provide Paragon 28, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- The HammerTube System has not been evaluated for safety and compatibility in the MR environment. The HammerTube System has not been tested for heating or migration in the MR environment.
- **Do not use other manufacturer's instruments or implants in conjunction with the HammerTube System**

MAINTAINING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of fixation devices.
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.

- The HammerTube implants are not intended to endure excessive abnormal functional stresses.
- The HammerTube implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique HammerTube System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28, Inc. recommends the use of Paragon 28, Inc. products in a sterile environment.

CLEANING AND DECONTAMINATION

All nonsterile implants and instruments must first be cleaned using established hospital methods before sterilization and introduction into a sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical detergents. Refer to the Paragon 28, Inc. **Reprocessing Instructions for Reusable Instruments** document P20-CLN-0001. This is also available by calling 855-786-2828.

STERILIZATION

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

| | |
|------------------|---------------|
| Sterilizer Type: | Pre-Vacuum |
| Temperature: | 270°F (132°C) |
| Time: | 4 Minutes |
| Dry Time: | 30 Minutes |

STERILE PRODUCT

Paragon 28 HammerTube implants are provided sterile using gamma irradiation. Packages for implants should be intact upon receipt. Once the seal of the product is broken, the product should not be re-sterilized.



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EC REP

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Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

CE 0086



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POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

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Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior.

WARNINGS AND PRECAUTIONS

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If corrective action is not taken, complications may occur.
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants and guide wires are intended for single use only.
- Instruments and K-wires are to be treated as sharps.
- **Do not use other manufacturer's instruments or implants in conjunction with the HammerTube™ System.**
- **Do not re-sterilize the HammerTube™ System implants.**

MR SAFETY INFORMATION

The HammerTube™ System has been evaluated for safety and compatibility in the MR environment. The HammerTube™ System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the HammerTube™ System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

MAINTAINING DEVICE EFFECTIVENESS

- The surgeon should have specific training, experience, and thorough familiarity with the use of fixation devices.
- The surgeon must exercise reasonable judgment when deciding which implant type to use for specific indications.
- The HammerTube™ implants are not intended to endure excessive abnormal functional stresses.
- The HammerTube™ implants are intended for temporary fixation only until osteogenesis occurs.
- Failure to use dedicated, unique HammerTube™ System instruments for every step of the implantation technique may compromise the integrity of the implanted device, leading to premature device failure and subsequent patient injury. Failed devices may require re-operation and removal.
- Carefully inspect the implants prior to use, inspect the instruments before and after each procedure to assure they are in proper operational condition. Instruments which are faulty, damaged or suspect should not be used.
- Paragon 28®, Inc. recommends the use of Paragon 28®, Inc. products in a sterile environment.

HANDLING AND STERILIZATION

STERILE PRODUCT

Paragon 28® HammerTube™ implants are provided sterile using gamma irradiation. Do not re-sterilize. SINGLE USE ONLY. The risk of re-use of device includes potential for patient to develop infection. Do not use implants after expiration date. Packages for implants should be intact upon receipt.

Implants in sterile packaging should be inspected to ensure that the package has not been damaged or previously opened. If the inner package integrity has been compromised, DO NOT USE THE IMPLANT. Contact the manufacturer for further instructions. The implants should be opened using aseptic technique. The implant should only be opened after the correct size has been determined. Once the seal of the product is broken, the product should not be re-sterilized.

All implants should be stored in a clean, dry environment.

NON-STERILE PRODUCT

Product that is presented in a tray is provided non-sterile. All non-sterile implants and instruments should be cleaned using established hospital methods before sterilization and introduction into the sterile surgical field. Compliance is required with the manufacturer's user instructions and recommendations for chemical

detergents. Refer to the Paragon 28®, Inc. *Instrument Reprocessing Instructions for Reusable Instruments* (P20-CLN-0001). This is also available by calling (855) 786-2828.

Unless specifically labeled sterile, the implants and instruments are supplied NONSTERILE and MUST be sterilized prior to use. Recommended sterilization methods include steam autoclaving after removal of all protective packaging and labeling. Prior to sterilization, verify that all instruments are in their open and unlocked position within the instrument tray(s). The use of an FDA cleared sterilization wrap is recommended. The following validated steam autoclave cycle is recommended:

| Method | Cycle | Temperature | Exposure Time | Dry Time |
|--------|------------|-----------------|---------------|------------|
| Steam | Pre-Vacuum | 270° F (132° C) | 4 Minutes | 30 Minutes |

INSTRUCTIONS FOR USE

The HammerTube™ System should only be implanted by surgeons who are fully experienced in the use of such implants and the required specialized surgical techniques. Refer to the HammerTube™ System Surgical Technique (P40-STG-0001) for complete instructions for use. For product information or to obtain a copy of the surgical technique manual, please contact Paragon 28®, Inc. by phone, (855) 786-2828.

IMPLANT REMOVAL

- Instrumentation can be provided for implant removal.
- Removal instructions are provided in the HammerTube™ System Surgical Technique (P40-STG-0001).

PRODUCT COMPLAINTS

The customer or health care provider should report any dissatisfaction with the product quality, labeling, or performance to Paragon 28®, Inc. immediately. Paragon 28®, Inc. should be notified immediately of any product malfunction by telephone or written correspondence. When filing a complaint, the name, part number and lot number of the part should be provided along with the name and address of the person filing the complaint.

Please contact company for product inquiries and surgical techniques, or to report any adverse experience.

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Symbol Explanations

| Symbol | Explanation | Symbol | Explanation |
|--------|------------------------------|---------------------------|---|
| | Authorized EU Representative | | Manufacturer |
| | Lot Number | | Non-sterile |
| | Item Number | | Do Not Reuse |
| | Consult IFU | R_x Only | For prescription use only |
| | Keep Dry | | Caution, consult accompanying documents |
| | Use By Date | STERILE R | Sterilized using irradiation |
| | Do Not Re-sterilize | | Do not use if package is damaged |